Telemonitoring of pulmonary function in patients with Cystic Fibrosis

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To assess whether internet-based telemonitoring of pulmonary function at home can prevent severe pulmonary exacerbations and lead to a reduction of hospital admission in patients with CF.

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON31622

Source
ToetsingOnline

Brief title
Tele 1

Condition

- Respiratory tract infections

Synonym
CF, Fibrocystic Disease of Pancreas, Mucosis, Mucovicidosis, Pancreatic Fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: onderhandelingen zijn nog gaande;mogelijk worden de spirometers in bruikleen verstrekt

Intervention

Keyword: Cystic Fibrosis, Pulmonary function, Telemonitoring

Outcome measures

Primary outcome

* Number of severe exacerbations; a severe exacerbation is defined as an exacerbation which requires treatment with intravenous antibiotic therapy, at the discretion of the treating lung physician.

* Number of moderate exacerbations; a moderate exacerbation is defined as exacerbation which allows treatment with oral antibiotic therapy, at the discretion of the treating lung physician.

Secondary outcome

* Quality of life, assessed with EQ-5D and Cystic Fibrosis Questionnaire (CFQ).

* Number and route of oral or intravenous antibiotic treatment

* Number of emergency room visits in case of suspicion of pulmonary exacerbation

* Compliance/adherence with self-testing spirometry assessed with a compliance survey

Study description

Background summary

The pathophysiology of CF is characterized by the development of mucus plugging in the airways and recurring lung infection. This leads to progressive worsening of the lung function, resulting in damage to the airways and, ultimately, death. Pulmonary disease in patients with CF is characterized by an

abnormal composition of the epithelial lining fluid. As a result, patients develop chronic airway infection and inflammation that starts early in life. During CF exacerbations, there is more sputum and more inflammation. During these episodes the condition of the patients deteriorates. These episodes are characterized by increased cough, difficulty to expectorate sputum, loss of appetite and fatigue, weight loss, decreased quality of life and decreases in spirometric parameters. Treatment normally consists of a temporarily treatment with specific antibiotic therapy based on a recent sputum culture. When the exacerbation is moderate, antibiotic treatment can be given at home (orally or intravenous), but when the exacerbation is severe, the patient must be admitted to the hospital for intravenous antibiotic treatment. Hospital admission has a great impact on the quality of life and well-being of a patient, because patients have to stay for about 3 weeks in a single room without contact with other patients to prevent cross-infection. Moreover, it is associated with high health care costs.Pulmonary function is an important measure of disease severity and prognosis in CF, and is routinely measured at each clinic visit every three months with spirometry. It has been suggested that pulmonary function usually deteriorates earlier than symptoms are perceived and reported. Recently, a new technology, internet based telemonitoring, has been developed to monitor pulmonary function at home by means of spirometry self-testing. Telemonitoring can attribute to an early diagnosis of an exacerbation and early treatment hereof. Severe exacerbations may be prevented so that the patient can remain at home as long as possible. This device has been shown useful in monitoring and treatment of patients with asthma and COPD, but its effectiveness has not yet been shown in CF patients.

Study objective

To assess whether internet-based telemonitoring of pulmonary function at home can prevent severe pulmonary exacerbations and lead to a reduction of hospital admission in patients with CF.

Study design

* Internet-based telemonitoring of pulmonary function by means of spirometry self-testing
* Lung function measurement will be performed with a handheld spirometer (Viasys healthcare, AM-2 Plus Pro).
* Each participating patient will be asked to fill in a symptom score (electronic) and then perform spirometry.
* The data will be transmitted to an external server (by modem) and accesable by internet afterwards.
* When there is an increase in symptoms or reduction in individual spirometry values (FEV1, FVC), a CF nurse will contact
the patient by phone. If treatment is indicated, it will be started immediately.

* In case of non-compliance an alert will be given. The patient will be contacted by phone to perform spirometry and assessment of symptoms.

Study burden and risks

* Confrontation with the (true) severity of the disease
* Weekly recurring act (measurement + forwarding)

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age 18 years or older

* Male or female
* Diagnosis of CF confirmed by sweat-test and/or DNA analysis and/or electrophysiology testing
* Stable disease
* Signed written informed consent.

Exclusion criteria

*Placing on the High Urgency waiting list for lung transplantation

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	28
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-02-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28124
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL20185.078.07
OMON	NL-OMON28124